DEVICE FOR SUTURELESS WOUND CLOSURE

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FIELD OF THE INVENTION

The present invention relates to a surgical fastener and technique for its use. Specifically, the invention is directed to a device to close wounds without the use of sutures.

DESCRIPTION OF THE PRIOR ART

Classical techniques to close wounds and incisions use sutures, basically using a needle and thread to sew the wound closed. While this technique acts to stitch the respective sides of the lesion together, it has several drawbacks. First, the tension required to pull the sides together is localized at the point of the stitch. This results in a tendency of the skin to tear around the stitch. Second, the skin may pouch out or sacculate between the stitches, greatly increasing the susceptibility of the wound to infection. Third, because the two sides of the wound are not evenly juxtaposed, scarring along the path of the sutures is increased. In addition, the placement of sutures requires deployment of needle and filament and afterward the tying off of the ends of the filament. This process is time consuming and requires workspace allowing dexterous manipulation.

Prior devices and techniques have been developed in an attempt to resolve these problems. These techniques range from superficial wound closure techniques to internal repair techniques. For example, U.S. Patent 3,971,384 to *Hasson* describes a surgical closure device designed to bring the two edges of a wound or incision together. A piece of surgical tape is secured on each side of the wound.

One piece of tape has an anchor for a tie strip secured to it while the other piece of tape has a slide secured to it. The tie strip has ratchet teeth on its dorsal surface such that the strip is inserted through the anchor end, across the wound and into the ratchet. The tape is then tightened and locked with the ratchet, bringing the two sides of the wound together. U.S. Patent 4,924,866 to *Yoon* describes a device for closing wounds comprising two arms connected by a hinged joint. The arms have a single pair of "skin engaging members" on the ventral surface such that when the device is placed over the wound, the members enter the skin, pulling the wound together underneath the joint.

While the devices described by *Hasson* and *Yoon* are directed to sutureless methods of wound closure, they suffer from certain defects. In particular, *Hasson* is limited to superficial applications where the tape can stick and, further, by the strength and size of the tape. The described device can receive no more force from the opposing sides of the wound than the tape can hold. In addition, the size of the device is limited by the size of the tape. The device of *Yoon* is similarly handicapped. First, the device is limited in its pliability by the structure of the arms. Second, the device is limited in its wound closure ability due to the limited number of "skin engaging members" in relatively close proximity to the wound. Third, because there is no ratcheting element, the sides of the wound must first be properly juxtaposed and aligned before its insertion as there is no second chance for its deployment.

Other devices have been described for internal tissue repair or reconstruction. They include U.S. Patent 6,241,747 to *Ruff*, which describes a barbed tissue connector for closing tissue wounds. The connector comprises an elongated shaft with pointed ends and a multitude of circumferentially placed barb-

like points along the length of the shaft. The shaft has a midline with the barbs on either side pointing away from the midline and toward the respective ends. In use, the tip of one end is inserted into one side of the wound. The wound is spread apart and the other end of the device inserted. After each end is inserted into the wound, the tissue is pressed together with the fingers to fully engage the barbs and bring the sides of the lesion into express contact. Because the device of *Ruff* has no dorsal or ventral surface, it must be placed deep enough in the lesion such that the tip of the circumferential barbs remains within the skin. Such means of insertion adds to the trauma already experienced by the tissue.

U.S. Patent Application Publication 0058966 to *Tormala et al.* describes a surgical fastener or implant for repairing tissue wounds, particularly torn menisci in the knee. The invention comprises a shaft with an arrow-like point on one end and a blunted barb on the other end. The barbs on both ends of the shaft are directed such that they point toward the ends of the shaft, thereby facilitating insertion and discouraging its removal. The barbed end of the device is passed through both ends of the cartilage where the ends are locked onto the shaft by the inwardly pointed ridges of the blunt end. The device described by *Tormala* requires use with a structure dense enough to have the device embedded within it and is thereby limited in its use.

SUMMARY OF THE INVENTION

The present invention is directed to a sutureless wound closure device that eliminates the pocketing and rupture associated with traditional sutures. Further, the device allows the tension, of pulling the opposing sides of the wound together, to be spread over a large area of the adjacent tissue. Also, the device is easy to use

and does not further increase the trauma already experienced by the underlying tissue.

In a preferred embodiment, the invention comprises a wound closure device for connecting tissue comprising a first and second strap, each strap including a ventral barbed surface. The straps are adjustably connectable to one another, whereby the straps form a wound closure.

In another preferred embodiment, the invention comprises a wound closure device for connecting tissue having a first flexible strap with a proximal end, distal end, ventral surface and dorsal surface. Also included is a second flexible strap also having a proximal end, distal end, ventral surface and dorsal surface. The proximal end of the second strap terminates in a connector designed and configured to adjustably connect to the proximal end of the first strap. Further, the first strap and the second strap have at least one barb on the ventral surface for engaging the tissue. By inserting each strap on either side of the wound, connecting the straps and adjusting them so as to bring the sides of the wound together, the straps form a wound closure.

In yet another version of the invention, the device comprises a first and second strap. Each strap includes a ventral surface having at least one barb, and a proximal and distal end. The distal end of each strap is placed in tissue surrounding the wound, and the proximal end of each first strap is designed and configured to be adjustably connected to the proximal end of each second strap. By connecting and adjusting the straps, the device forms a wound closure.

The advantages of the invention are manifold. First, from a clinical standpoint, the invention helps to limit rupture of the wound. Second, from a cosmetic standpoint, the invention greatly limits scarring by reinforcing the subcutaneous fascia and eliminating sutures. Third, due to the above two advantages, the invention greatly reduces infection. Fourth, the invention is less painful and the patient heals faster than traditional wound closure methods because staples or sutures, piercing through the underlying muscle, are not required.

The invention can also be used in most settings and locales from acute and field conditions to chronic conditions treated in care facilities. For example, the invention can be used for closure of small laparoscopy ports, which is difficult, particularly in obese patients. In these conditions, standard suturing through a small skin incision is very difficult and takes significant time or requires a larger skin incision to be made. Thus, the invention can make more demanding procedures easier and allow time-consuming procedures to be performed in more urgent situations.

The invention also allows greater blood flow to the healing tissue. When a conventional stitch is used under high tensions, it results in blood being cut off to the tissue encircled by the loop of the stitch. In contrast, by using the present invention, this problem is alleviated. Allowing greater blood flow to the incision reduces scarring and results in much better results, particularly with cosmetic surgery.

Further, the straps can be modified. Such modifications can allow the use of the invention in tightening waistlines, which have been stretched by injury, surgery or childbirth. The straps can also be applied to the top of a hernia repair

to reduce risk of recurrence or adapted to facilitate a sternotomy closure, which would stabilize the chest and reduce discomfort after open-heart surgery.

The objects and advantages of the invention will appear more fully from the following detailed description of the preferred embodiment of the invention made in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of the first strap being inserted into the connector of the second strap and adjusted, thereby closing the wound.

Fig. 2a is a partial side elevation view of the first strap of the device at the proximal end.

Fig. 2b is a ventral elevation view of the strap of **Fig. 2a**.

Fig. 2c is a partial side elevation view of the second strap of the device at the proximal end.

Fig. 2d is a ventral elevation view of the strap of **Fig. 2c**.

Fig. 3a is a side elevation illustrating the flexion of the barbs of the closure device while stored in a trochar.

Fig. 3b is a perspective view of the device being deployed out of the trochar, shown in a cut-away view, with the barbs of the device being unflexed.

DETAILED DESCRIPTION OF THE INVENTION

Referring now to **Fig. 1**, there is illustrated a perspective view of a preferred embodiment of the disclosed invention **10**. As illustrated, the invention **10** includes a first strap **14** and a second strap **30**. The first strap **14** and the second strap **30** include distal ends **62** and **63** and proximal ends **18** and **34**, respectively. The straps **14** and **30** are planar and made of a pliable material having dorsal surfaces **20** and **36** and a ventral surface **22** and **38**. The dorsal surface **20** and **36** of the straps **14** and **30** are smooth while the ventral surfaces **22** and **38** include a plurality of small barbs **24** and **40** which project downward from the ventral surface **22** and **38** and curve toward the proximal end **18** and **34**. In one preferred embodiment, the straps **14** and **30** have a length of about 4 cm and a width of about 0.5 cm. In other embodiments, the straps **14** and **30** may be larger or smaller to accommodate a wound, illustrated at **48**. Although the shape of the straps **14**, **30** may include planar sides as illustrated in **Fig. 1**, it is within the scope of the present invention for each strap to have a rounded configuration.

As shown in **Fig. 1** and **Figs. 2a** and **b**, the proximal end **18** of the first strap **14** is tapered along its planar sides, and the ventral surface **22** is composed of a plurality of small teeth or ratchets **26**. The ratcheted surface may comprise about between 1 and 20 mm of the proximal end **18** of the first strap **14**. Between the end of the ratcheted surface and the beginning of the barbs **24**, there is a gap space **16** on the ventral surface **22**, which is smooth and has no protuberances.

Fig. 1 and **Fig. 2c** and **d** illustrate a preferred version of the second strap **30**. In this version the proximal end **34** of the second strap **30** terminates in a buckle **42**. However, in other versions, the proximal end **34** may terminate in any

other form of connector, which may be capable of adjustably connecting the two straps such as VELCRO, adhesives or clips. Between the buckle **42** and the most proximal of the barbs **40** is a gap space **32** marked by a smooth region of the ventral surface.

As illustrated in **Fig. 1** the invention **10** is deployed in a lesion or wound **48**. In use, the first strap **14** and the second strap **30** of the device **10** are placed on either side of the wound **48** in an orientation perpendicular to the axis of the wound **56**. In a preferred embodiment, the straps **14** and **30** are inserted underneath the epidermis directly above the fascia **50** of the surrounding tissue. The distal end **62** and **63** of each strap **14** and **30** are directed away from the lesion while the proximal ends **18** and **34** of the straps **14** and **30** are situated at about the midline **56** of the wound **48**. The straps **14** and **30** are displaced on either side of the wound **48** such that the gap space **16** and **32** of each strap **14** and **30** is generally behind the edge of the wound **48**. The barbs **24** and **40** are then gently embedded in the underlying tissue, which in a preferred version of the invention is the fascia **50**, so that the straps **14** and **30** engage the tissue.

Fig. 1 shows the barbs **24** and **40** of the straps **14** and **30** engaged in the fascia **50** with the barbs **24** and **40** pointed toward the midline **56** of the wound **48**. The two straps **14** and **30** are connected at their proximal ends **18** and **34** and adjusted to a desired tightness. Illustrated is one preferred version of the invention showing the straps **14** and **30** that are tightened by pulling the proximal end **18** of the first strap **14** through the buckle **42** along the path designated by the arrow **19**. The buckle **42** is then tightened by urging it distally on the ratchets **26** of the first strap **14**. Tightening or putting tension on the proximal ends **18** and **34** of the

straps **14** and **30** pulls the underlying fascia **50** of the wound together, allowing a smooth joining of the tissue surrounding the wound **48**.

When the wound is large or the tissue is delicate, multiple straps **14** and **30** may be needed. When multiple straps are used, the straps **14** and **30** are deployed on either side of the wound **48**. When all the straps **14** and **30** are deployed along the length of the lesion, the tapered, proximal end **18** of each first strap **14** is inserted into the buckle **42** of the respective second strap **30** until the locking tongue **44** engages the ratchets **26** of the first strap **14**. In a particularly preferred version, the locking action of the first proximal end **18** in the buckle **42** is like that of a nylon tie such that once the tongue **44**, illustrated in **Fig 2d,** is engaged with the ratchets **26**, the tension on the straps **14** and **30** can be increased by pulling the proximal end **18** through the buckle **42** in the direction of the arrow **19**. The process of pulling the proximal end **18** of the first strap **14** through the buckle **42** of the second strap **30** of each of the respective first **14** and second **30** pair of straps, allows the opposing sides of the wound **48** to be brought close enough to begin tightening the individual straps in a sequential fashion until the opposing sides of the wound **48** are brought together.

Because the barbs **24** and **40** continue into the tissue surrounding the wound along the length of the straps **14** and **30**, the tension loaded on the straps **14** and **30** is transferred to the underlying tissue assuring a smooth juxtaposition of the opposing sides of the wound **48**. It will be appreciated that depending on the size of the wound **48**, more or less straps **14** and **30** may be needed. For example, a very large wound **48** will require a large number of straps **14** and **30** while a small wound **48** will require one or a few straps **14** and **30**. Similarly, very delicate or

visible tissue may require many small straps **14** and **30** while tough or concealed tissues may require fewer large straps **14** and **30**.

As shown in **Fig. 1**, the barbs **24** and **40** are conical in shape, ending at a point. The barbs **24** and **40** are designed to be pliable yet have stiffness such that they can pierce tissues ranging from muscle to skin to fat. Such barbs can be made from nylon, plastics and resorbable polymers such as polyglycolic acid and poly-L lactic acid, for instance. The barbs **24** and **40** may have a slightly different shape, depending on the particular tissue to be used in. For example, straps to be used in adipose tissue **52** may have barbs **24** and **40** that are longer and broader because the tissue is soft while barbs **24** and **40** to be used in muscle **54** or connective tissue, such as the fascia **50**, may be shorter and narrower because those tissues are tough, and the barbs **24** and **40** do not need to project far into the tissue to embed. Nevertheless, the barbs **24** and **40** should generally be about between 2.5 mm long and 4.0 mm long and have a circumference around the base of about 2-3 mm. Further, while one exemplary version of the invention has only one barb **24** and **40** per row along the horizontal axis of the straps **14** and **30**, in other exemplary versions, there may be several barbs **24** and **40** per row arranged along the ventral surface **22** and **38** of the straps **14** and **30**.

Figs. 2 a-d illustrate a particularly preferred version of the proximal ends **18** and **34** of the first and second straps **14** and **30**. **Figs. 2a** and **2b** show a side and ventral elevation, respectively, of the proximal end **18** of the first strap **14**. As shown, the first strap **14** is tapered toward the proximal end **18** and has a series of small ratchet-like protrusions **26** on its ventral surface **22** while the dorsal surface **20** is flat. **Figs. 2c** and **2d** show a side and ventral elevation, respectively, of the proximal end **34** of the second strap **30**. **Fig. 2c** shows the dorsal surface **36** and

the ventral surface **38** with the buckle **42** terminating the proximal end **34** of the second strap **30**. **Fig. 2d** illustrates the ventral surface **38** of the proximal end **34** of the second strap **30** with the buckle **42** terminating the proximal end and a locking tongue **44** situated within the buckle **42**.

Methods to aid in deployment of the invention **10** are also included. For example, **Fig. 3a** illustrates the strap **14** inside a trochar **60**. For the purposes of the drawing, only the second strap **14** is illustrated. However, both the first strap **14** and the second strap **30** are deployed with the trochar **60** and will have similar dimensions with comparable distal ends **62** and **63** as shown in **Fig 1**. The trochar **60** is a cylindrical tube having walls **64** fabricated from a material stiff enough to use as an applicator. In particularly preferred versions, the trochar **60** may be made of, plastic or metal and will have a diameter slightly greater than the width of the straps **14** and **30** it is used to deploy. While in the trochar **60**, the barbs **24** and **40** are flexed upward due to the slightly greater length of the barbs compared to the height of the trochar **60**. The trochar **60** may serve both to store the straps **14** and **30** in and as an applicator for the straps **14** and **30**. In situations where the trochar **60** is disposable, the straps would come stored in the trochar. In situations where the trochar **60** is reloadable, the straps **14** and **30** and the trochar **60** may be stored separately.

Fig. 3b illustrates the movement of the barbs **24** and **40** downward, shown by the arrows **70,** as the straps **14** and **30** are slid out of the opening **61** of the trochar **60**. In a preferred version of the invention, the straps **14** and **30** are deployed by sliding the end of the trochar **60** containing the distal end **62** of the strap **14** and **30** between the fascia **50** and the overlying adipose layer **52** of the tissue of the wound **48** (shown in **Fig. 1**). The distal ends **62** or **63** of the straps **14**

or **30** are then urged out of the trochar **60** from the proximal end **18** or **34** in the direction of the arrow **66**, deploying the most distal barbs **24** and **40** into the fascia **50**. The trochar **60** is then pulled off the remainder of the strap **14** or **30**, in the direction of the arrow **68**, embedding the barbs **24** and **40** in the underlying fascia **50**. This process is repeated for the opposing strap such that the proximal end **18** of the first strap **14** and the proximal end **34** of the second strap **30** abut each other at about the midline **56** of the wound **48**. The proximal end **18** of the first strap **14** is then inserted in the buckle **42** of the second strap and tightened by pulling the first strap **14** in the direction of the arrow **19** as previously described.

It is a further facet of the invention **10** that while, in a preferred embodiment, the straps **14** and **30** are deployed subcutaneously in the fascia **50**, as shown in **Fig 1.**, the straps may also be deployed on the surface of the skin with the barbs **24** and **40** engaged with the epidermis. The straps **14** and **30** may also be used internally in most situations where conventional stitches are used such as during exploratory surgery or resections, and with most tissues, including connective tissues, such as tendons, cartilage, ligaments and adipose tissue.

It is yet another facet of the invention **10** that the straps **14** and **30** are made out of any hypoallergenic material and may be resorbable or permanent. In some instances, the straps **14** and **30** may not be resorbable and will remain engaged in the lesion or wound **48,** such as permanent sutures are, or until the care provider elicits their removal. In other versions of the invention, the straps may be made of resorbable materials such as those described in U.S. Patents 4,968,317 to *Tormala et al.* or 4,898,186 to *Ikada et al.*, both hereby incorporated by reference for their description of such materials.

It is understood that the invention is not confined to the particular construction and arrangement of parts herein illustrated and described but embraces such modified forms thereof as come within the scope of the following claims.